510(k) SUMMARY K061199

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Applicant:

Braun GmbH
Frankfurter Strasse 145
61476 Kronberg
Germany

MAY 3 1 2006

Application Correspondent:

Amanda Heffernan
Manager, Regulatory Affairs
Clinical Research & Dental affairs
The Gillette Company
800 Boylston Street
Prudential Tower Building, Floor 46
Boston, MA 02199-8004

Telephone: 617.463.9532
Fax: 617.463.9578
Email: amanda_heffernan@gillette.com

Date summary prepared: November 3, 2005

Proprietary name of device: Oral-B® ProfessionalCare™Series/
Oral-B® AdvancePower™Series powered toothbrush

Generic /classification name: Toothbrush, Powered

Product code (classification): JEQ (Class 1, 21 C.F.R. 872.6865)

Legally Marketed Predicate Devices:

- Sonicare® Advance Toothbrush (K040416)
  Philips Oral Healthcare, Inc.

- Oral-B® ProfessionalCare™Series/Oral-B® AdvancePower™Series
  Braun GmbH

Device Description and Technological Characteristics:

Oral-B® ProfessionalCare/Oral-B® AdvancePower is a rechargeable electric toothbrush comprised of a charging unit and a rechargeable power unit. The rechargeable power unit is inductively charged and therefore electrically safe in accordance with the Second Edition of the standard for Personal Hygiene and Health Care appliances, UL 1431. The Oral-B® ProfessionalCare/Oral-B® AdvancePower electric toothbrush has an oscillating/rotating technology, a small round brush head that aids tooth-to-tooth cleaning. The brush head is designed to facilitate deeper penetration of interdental areas. The action of the brush head has an oscillation range frequency between 63 to 73 Hz with a vibration frequency of 340 Hz (3800 strokes per minute) and an oscillating range angle of 42° to 60° depending on the toothbrush model.

The brush head design is a small circular brush head and features an arrangement of flagged bristles and power tips. The power tips have tufts of longer bristles on either side of the brush head in the outer ring. These power tips have a wear indicator function and are colored with the FDA approved colorant FD&C blue No.2.

510(k) SUMMARY Cont'd

The flagged bristle tufts have tetralocular filaments and are designed to increase the brushing and polishing action on tooth surfaces. The bristle material is Polyamid or PA6.12. The toothbrush features a round handle with anti-slip characteristics for better control in wet conditions and offers a variable range of speeds to best meet individual needs.

While power toothbrushes are 510(k) exempt device, we believe the expanded indication for use of treating and preventing gingivitis may exceed the limitation for 510(k) exemption. The expanded indications for use (i.e., treating and preventing gingivitis) are the only changes from the currently marketed devices Oral-B® ProfessionalCare™Series/Oral-B® AdvancePower™Series. There are no changes to the design, materials or manufacturing process of these devices.

Indications for Use:
To promote good oral hygiene, including plaque removal and treating and preventing gingivitis.

Testing:

Oral-B® ProfessionalCare™Series/Oral-B® AdvancePower™Series powered toothbrushes have been tested in numerous controlled clinical studies. These trials evaluated oral soft and hard tissue for safety, plaque, gingivitis and bleeding. Collectively, these studies demonstrate that the Oral-B® ProfessionalCare™Series/ Oral-B® AdvancePower™Series powered toothbrush is effective at treating and preventing gingivitis.

Quality assurance testing on the Oral-B® ProfessionalCare™Series/Oral-B® AdvancePower™Series electric toothbrush has been conducted to ensure the integrity of products.

Oral-B® Professional Care™ Series/Oral-B® AdvancePower™ Series products are rechargeable battery operated toothbrushes. The toothbrush handles are inductively charged so there is no electrical connection between the charger and handle. All electrical components are housed within thermoplastic enclosures and the product is provided with a Listed 1flexible supply cord terminating in a parallel blade attachment plug for connection to a nominal 100-120 V, 50-60 Hz supply source.

Oral-B® Professional Care™ Series/Oral-B® AdvancePower™ Series products are evaluated and comply with the applicable requirements to bear the Underwriters Laboratories Inc. Mark (UL 1431).

Conclusions:

The results from these tests support the safety and effectiveness of Oral-B® ProfessionalCare™ Series/Oral-B® AdvancePower™ Series power toothbrush and its substantial equivalence to the predicate device without raising new safety or effectiveness issues.

Bibliography

1. Cronin M, Dembling W, Warren P, King D.; A 3-month clinical investigation comparing the safety and efficacy of a novel electric toothbrush [Braun Oral-B 3D Plaque Remover] with a manual toothbrush. *Am J Dent* 1998; 11: (Spec Iss):S17-S21.

2. Haffajee A, Thompson M, Torresyap G, Guerrero D and Socransky S.; Efficacy of manual and powered toothbrush (I). Effect on clinical parameters. J Clin Periodontol 2001; 28: 937-946

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6. Van der Weijden G.A., Timmerman M.K., Piscaer M., Ijzerman Y., Warre P.R., Van der Velden U.; A clinical comparison of three powered toothbrushes. J Clin Periodontol 2002; 29: 1042-1047.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2006

Braun GmbH
C/O Ms. Amanda Heffernan
Manager, Regulatory Affairs
The Gillette Company
800 Boylston Street
Prudential Tower Building FL 46
Boston, Massachusetts 02199-8004

Re: K061199
Trade/Device Name: Oral-B® Professional Care™ Series/Oral-B® AdvancePower™ Series
Regulation Number: 872.6865
Regulation Name: Powered Toothbrush
Regulatory Class: I
Product Code: JEQ
Dated: March 20, 2006
Received: March 28, 2006

Dear Ms. Heffernan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

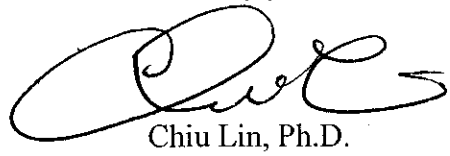
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0

Indications for Use

510(k) Number (if known): _____

Device Name: **Oral-B® Professional Care™ Series/Oral-B® AdvancePower™ Series**

Indications for Use: To promote good oral hygiene including plaque removal and treating and preventing gingivitis.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runge

...on Sign-Off)
...t of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number: K061199